

Consolidated Guidance About Materials Licenses Program: Specific Guidance About Self-Shielded Irradiator Licenses Draft Report for Comment (NUREG-1556, Vol. 5)

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Abstract

As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses," dated October 1997, is the fifth program-specific guidance developed for the new process and is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States. This document combines and updates the guidance found in Regulatory Guide 10.9, Revision 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators," dated December 1988, and in NMSS Policy and Guidance Directive FC 84-16, Revision 1, "Standard Review Plan for Applications for Use of Self-Contained Dry Source-Storage Gamma Irradiators," dated January 26, 1989. This draft report takes a more risk-informed, performance-based approach to licensing self-shielded irradiators, and reduces the information (amount and level of detail) needed to support an application to use these devices. Note that this document is strictly for

public comment and is *not* for use in preparing or reviewing self-shielded irradiator licenses until it is published in final form.

Foreword

The United States Nuclear Regulatory Commission (NRC) is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a list of volumes currently included in the NUREG-1556 series:

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Draft for Comment
3	Applications for Sealed Source and Device Evaluation and Registration	Draft for Comment
4	Program-Specific Guidance About Fixed Gauge Licenses	Draft for Comment

The current document, draft NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiators," dated October 1997, is the fifth program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It combines and updates the guidance for applicants and licensees previously found in Regulatory Guide 10.9, Revision 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators," dated December 1988, and the guidance for licensing staff previously found in Policy and Guidance Directive FC 84-16, Revision 1, "Standard Review Plan for Applications for Use of Self-Contained Dry Source-Storage Gamma Irradiators," dated January 26, 1989. In addition, this draft report also contains pertinent information found in Technical Assistance Requests and Information Notices, as listed in Appendix A.

Since this draft report takes a risk-informed, performance-based approach to licensing self-shielded irradiators, it reduces the amount of information needed from an applicant seeking to possess and use a relatively safe device. These self-shielded irradiators containing sealed sources of radioactive material incorporate features engineered to enhance their safety. NRC's considerable experience with these

licensees indicates that radiation exposures to workers are generally low, if the irradiators operate as designed and workers follow basic safety procedures.

A team composed of NRC staff from headquarters and regional offices drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to self-shielded irradiators. A representative of NRC's Office of the General Counsel provided a legal perspective.

Draft NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiators Licenses," dated October 1997, represents a step in the transition from the current paper-based process to the new electronic process. This draft document is available on the Internet at the following address:
<http://www.nrc.gov/NRC/NUREGS/SR1556/V5/index.html>.

This draft report is strictly for public comment and is *not* for use in preparing or reviewing applications for self-shielded irradiators until it is published in final form. It is being distributed for comment to encourage public participation in its development. NRC is requesting comments such as whether a risk-informed, performance-based approach to licensing is valid, as well as comments on the information provided about self-shielded irradiators. Please submit comments within 90 days of the draft report's publication. Comments received after that time will be considered if practicable.

Address comments to: Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand deliver comments to 11545 Rockville Pike, Rockville, Maryland, between 7:15 a.m. and 4:30 p.m. on Federal workdays. Comments may also be submitted through the Internet by addressing electronic mail to dlm1@nrc.gov.

Draft NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses," dated October 1997, is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this draft report are provided for information and comment only.

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Figures

1.1 Types of Irradiators. The irradiator on the far left is used to calibrate dosimetry devices, while the other two units are research irradiators.

2.1 U.S. Map. Location of NRC Offices and Agreement States. As of October 1, 1998, the Walnut Creek Field Office will close. All communications should be forwarded to Region IV.

8.1 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

8.2 Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories.

8.3 Annual Dose Limits for Radiation Workers.

8.4 Proper Location of Irradiator. Irradiators should be located away from occupied areas and secured to prevent authorized use or removal.

8.5 Proper Handling of Incident. Licensee personnel implement emergency procedures when a flammable sample catches fire.

8.6 Routine Maintenance and Lubrication. To ensure proper operation of the unit, self-shielded irradiator licensees need to perform

routine maintenance according to the manufacturer's written instructions and recommendations.

8.7 Non-Routine Maintenance. For non-routine maintenance, most licensees rely on the manufacturer or other service companies.

M.1 Diagram of Office and Irradiator Area.

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ITEMS 5 & 6: Materials to be Possessed and Proposed Uses

ITEMS 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal

Table M.2 Calculational Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator

Table M.3 Calculational Method, Part 2: Annual Dose Received from Self-Shielded Irradiator

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Abbreviations

ALARA As low as is reasonably achievable

ANSI American National Standards Institute

bkg Background

BPR Business Process Redesign

Bq Becquerel

CFR Code of Federal Regulations

cpm	Counts per minute
DOE	United States Department of Energy
DOT	United States Department of Transportation
FDA	United States Food and Drug Administration
G-M	Geiger-Mueller
GPO	Government Printing Office
IN	Information Notice
mGy	Milligray
mR	Milliroentgen
mrem	Millirem
mSv	Millisievert
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	Optical character reader
OMB	Office of Management and Budget
OSP	Office of State Programs
QA	Quality Assurance
REV	Revision
RG	Regulatory Guide
RQ	Reportable Quantities
RSO	Radiation Safety Officer
SDE	Shallow Dose Equivalent
SFPO	Spent Fuel Project Office
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)

SSD	Sealed Source and Device
std	Standard
Sv	Sievert
TAR	Technical Assistance Request
TEDE	Total effective dose equivalent
TI	Transportation Index
TLD	Thermoluminescent dosimeters
USDA	United States Department of Agriculture

1 Purpose of Draft Report

This document is strictly for public comment and is ***not*** for use in preparing or reviewing applications for self-shielded irradiators until this document is published in final form.

This draft report provides guidance to an applicant in preparing a self-shielded irradiator license application as well as NRC criteria for evaluating a self-shielded irradiator license application. It is not intended to address the research and development or the commercial aspects of manufacturing, distribution, and service of self-shielded irradiators and their associated sources. Within this document, the phrases or terms, "self-shielded irradiator," "self-contained irradiators," or "irradiators" are used interchangeably.

Irradiators are used for a variety of purposes in research, industry, and other fields. Typical uses are:

- Sterilizing or reducing microbes in medical and pharmaceutical supplies;
- Preserving foodstuffs;
- Studying radiation effects;
- Synthesizing and modifying chemicals and polymers;
- Eradicating insects through sterile male release programs; and
- Calibrating thermoluminescent dosimeters (TLDs).

The American National Standards Institute (ANSI) has developed and published safety standards for gamma irradiators. In determining basic safety requirements, ANSI divided all gamma irradiators into four general categories. This draft NUREG report deals with the type of irradiator discussed in ANSI Standard N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)."⁽¹⁾ This draft report also uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: "[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration."

Depending on the design, the radiation source within the irradiator may be in a fixed position or may be movable. In the latter case, interlocks are used to ensure that the source does not move into a position that, during normal use of the irradiators, may cause a radiation hazard to any individual. Bypassing or failure of an interlock could cause persons to be exposed to high levels of radiation.

Self-shielded irradiators typically contain several hundred to several thousand terabecquerels (curies) of cesium-137 (Cs-137) or cobalt-60 (Co-60) and range in weight from several hundred to several thousand kilograms (pounds). Other irradiators contain megabecquerel (millicurie) quantities of strontium-90 (Sr-90), a beta emitter, and are used primarily for thermoluminescent dosimeter (TLD) calibration.

The NRC's past practice was to issue a separate license to authorize the possession and use of self-shielded irradiators if any of the units exceeded 37 terabecquerels (1,000 curies). NRC will now authorize self-shielded irradiators on the same license as the licensee's other licensed material.

This draft report identifies the information needed to complete [NRC Form 313](#) (Appendix B), "Application for Material License," for the use of sealed sources in self-shielded irradiators. The information collection requirements in 10 CFR Part 30 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0017, and 3150-0120, respectively.

The format within this document for each item of technical information is as follows:

- Regulations -- references the regulations applicable to the item;
- Criteria -- outlines the criteria used to judge the adequacy of the applicant's response;
- Discussion -- provides additional information on the topic sufficient to meet the needs of most readers; and
- Response from Applicant -- provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and References are self-explanatory and may not be found for each item on [NRC Form 313](#).

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; as indicated on the form, the answers to those items are to be provided on separate sheets of paper and submitted with the completed NRC Form 313. For the convenience of applicants and for streamlined handling of self-shielded irradiator applications in the new materials licensing process, use Appendix C to provide supporting information, attach it to NRC Form 313, and submit them to NRC.

Appendixes D through P contain additional information on various radiation safety topics. Appendix Q is a sample self-shielded irradiator license; it contains the conditions most often found on these licenses, although not all licenses will have all conditions. Appendix R is a checklist that NRC staff uses to review applications and applicants can use to check for completeness.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. These terms are defined in 10 CFR Part 20. Rem, and its SI equivalent Sievert (1 rem = 0.01 Sievert (Sv)), is used to describe units of radiation exposure or dose. This is because 10 CFR Part 20 sets dose limits in terms of rem, not rad or roentgen, and the sealed sources used in irradiators emit beta and gamma rays, which means that 1 roentgen = 1 rad = 1 rem.

2 Agreement States

Certain states, called Agreement States (see [Figure 2.1](#)), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant other than a Federal agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that State for guidance on preparing an application; file these applications with State officials, not with the NRC.

In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct

licensed operations. NRC recommends that licensees ask their local contact for the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996, which is available from NRC upon request.

Table 2.1 provides a quick way to check on which agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, US territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site <i>not</i> subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

Figure 2.1 U.S. Map. Location of NRC Offices and Agreement States. As of October 1, 1998, the Walnut Creek Field Office will close. All communications should be forwarded to Region IV.

References: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional or Field Offices. Or visit the NRC Office of State Programs' (OSP's) Home Page (<http://www.hsrdo.org/nrc/home.htm>) and choose "Directories."

All Agreement States Letter, SP-96-022, dated February 16, 1996, is available by calling OSP; call NRC's toll free number (800) 368-5642 and then ask for extension 415-3340. Or visit OSP's Home Page (<http://www.hsrdo.org/nrc/home.htm>) , choose "NRC-State Communications," then choose "All of the Above," and follow the directions for submitting a query for "SP96022."

3 Management Responsibility

The NRC recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. NRC believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. NRC also believes that effective management will result in increased safety and compliance.

"Management" refers to the processes for conducting and controlling the radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license and application;
- Meticulous compliance with current NRC and DOT regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained; and
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, dated June 1995, and Manual Chapter 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes"; see Notice of Availability (on inside front cover of this draft report). NUREG-1600 is also available on the Internet. Visit NRC's Home Page (<http://www.nrc.gov/>), choose "Nuclear Materials," then "Enforcement," "Enforcement Guidance Documents," and then "Enforcement Policy."

4 Applicable Regulations

It is the applicant's or licensee's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to self-shielded irradiators:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders";
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations";
- 10 CFR Part 20, "Standards for Protection Against Radiation";
- 10 CFR Part 21, "Reporting of Defects and Noncompliance";
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material";
- 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material";
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Part 71 requires that licensees who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable requirements of the United States Department of Transportation (DOT) that are found in 49 CFR Parts 170 through 189. Copies of DOT regulations can be ordered from the Government Printing Office (GPO) whose address and telephone number are listed below.

- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"; and
- 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC."

To request copies of the above documents, call GPO's order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199 from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. You may also contact the GPO electronically at www.gpo.gov. Request single copies of the above documents from NRC's Regional or Field Offices (see [Figure 2.1](#) for addresses and telephone numbers). Note that NRC publishes amendments to its regulations in the Federal Register.

5 How to File

5.1 Paper Application

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete [NRC Form 313](#) (Appendix B) Items 1 through 4, 12, and 13 on the form itself.
- Complete [NRC Form 313](#) Items 5 through 11 on supplementary pages or use Appendix C.
- For each separate sheet, other than Appendix C, that is submitted with the application, identify and key it to the item number on the application or the topic to which it refers.
- Submit all documents, typed, on 8-1/2 x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application and one copy.
- Retain one copy of the license application for future reference.

As required by 10 CFR 30.32(c), applications must be signed; see section on "Certification."
Using the suggested wording of responses and committing to using the model procedures in this draft report will expedite NRC's review.

All license applications will be available for review by the general public in NRC's Public Document Rooms. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application.

Employee personal information, i.e., home address, home telephone number, social security number, date of birth, radiation dose information, should not be submitted unless specifically requested by NRC.

As explained in the "Foreword," NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper applications. However, these will be

scanned and put through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as **Arial, Futura, Univers**; the text of this document is in a serif font called **Times New Roman**.
- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5.2 Electronic Application

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or CD-ROM, and through the Internet. Additional filing instructions will be provided as these new mechanisms become available. The existing paper process will be used until the electronic process is available.

6 Where to File

Applicants wishing to possess or use licensed material in any State or U.S. territory or possession subject to NRC jurisdiction must file an application with the NRC Regional Office for the locale in which the material will be possessed and/or used. [Figure 2.1](#) shows NRC's four Regional Offices and their respective areas for licensing purposes and identifies Agreement States. The Walnut Creek, California, Field Office, can respond to routine telephone inquiries until September 30, 1998. Effective October 1, 1998, the Walnut Creek, California, Field Office will close and any communications previously involving that Field Office should be addressed to the Region IV Office.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State,

not NRC. However, if work will be conducted at Federally controlled sites in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. See the section on "Agreement States" for additional information.

7 License Fees

Each application for which a fee is specified, including applications for new licenses and license amendments, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded; application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for additional information on exemptions from annual fees and 10 CFR 171.16© on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of [NRC Form 313](#) (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC headquarters in Rockville, Maryland, (301) 415-7554. You may also call NRC's toll free number (800) 368-5642 and then ask for extension 415-7554.

8 Contents of an Application

The following comments apply to the indicated items on [NRC Form 313](#) (Appendix B).

8.1 Item 1: License Action Type

THIS IS AN APPLICATION FOR (Check appropriate item)

TYPE OF ACTION	LICENSE NO.
<input type="checkbox"/> A. New License	Not applicable
<input type="checkbox"/> B. Amendment to License No.	XX-XXXXXX-XX
<input type="checkbox"/> C. Renewal of License No.	XX-XXXXXX-XX

Check box A for a new license request.

Check box B for an amendment⁽²⁾ to an existing license, and provide license number.

Check box C for a renewal⁽²⁾ of an existing license, and provide license number.

8.2 Item 2: Applicant's Name and Mailing Address

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Note: NRC must be notified before control of the license is transferred or when bankruptcy proceedings have been initiated. See below for more details. NRC IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

Timely Notification of Transferring Control

Regulations: 10 CFR 30.34(b).

Criteria: Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license, or, as some licensees call it, "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior NRC written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the self-shielded irradiator; and
- Public health and safety are not compromised by the use of such materials.

Response from Applicant: None from an applicant for a new license; Appendix D, excerpted from Information Notice (IN) 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, identifies the information to be provided about transferring control.

References: See the Notice of Availability (on the inside front cover of this draft report) to obtain copies of IN 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, and IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997.

Notification of Bankruptcy Proceedings

Regulations: 10 CFR 30.34(h).

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Response from Applicant: None at time of application for a new license. Generally, licensees should notify NRC within 24 hours of filing a bankruptcy petition.

8.3 Item 3: Address(es) where Licensed Material will be used or Possessed

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Any town, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A Post Office Box address is not acceptable.

To allow licensees greater flexibility, the applicant should *not* identify the self-shielded irradiator location by room number and should *not* submit drawings of the location within the facility. The acceptability of the irradiator's location will be reviewed during the

inspection process; see section on "Facilities and Equipment" for additional information.

When a new self-shielded irradiator is acquired and will be used at the facility address listed in the license, the license need *not* be amended. An NRC-approved license amendment *is* required before locating an irradiator at an address not already listed on the license, whether that irradiator is an additional unit or a relocation of an existing unit.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Note: As discussed later under "Financial Assurance and Record Keeping for Decommissioning," licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For self-shielded irradiator licensees, acceptable records are sketches or written descriptions of the specific locations where each irradiator is used or stored and any information relevant to damaged devices or leaking radioactive sources.

8.4 Item 4: Person to be Contacted about this Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed Radiation Safety Officer (RSO), unless the applicant has named a different person as the contact. The NRC will contact this individual if there are questions about the application.

Notify NRC if the contact person or his or her telephone number changes so that NRC can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

As indicated on [NRC Form 313](#) (Appendix B), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C for this purpose and should note that using the suggested wording of responses and committing to using the model procedures in this draft report will expedite NRC's review.

8.5 Item 5: Radioactive Material - Sealed Sources and Devices

Regulations: 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210.

Criteria: Applicants must provide the manufacturer's name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: NRC or an Agreement State performs a safety evaluation of self-shielded irradiators before authorizing a manufacturer to distribute the irradiators to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the formalization of the SSD registration process, some older irradiators may have been specifically approved on a license. Licensees can continue to use those units specifically listed on their licenses. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a license.

As explained in an "Urgent Notice" with an enclosed Order, both dated July 3, 1984 (see Appendix E), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism which would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses that authorize J.L. Shepherd Mark I or Model 81-22 irradiators. Applicants wishing to use either of these models must comply with the Order's requirements.

Consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. To ensure that applicants use irradiators according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer.

Response from Applicant:

- Identify each radionuclide that will be used in each source in the self-shielded irradiators.
- Provide the manufacturer's name and model number for each sealed source and device requested.
- Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State.
- Confirm that the activity per source and maximum activity in each irradiator will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.

Note: For information on SSD registration certificates, contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.

8.6 Item 5: Radioactive Material - Financial Assurance and Record Keeping for Decommissioning

Regulations: 10 CFR 30.34(b), 10 CFR 30.35.

Criteria: Self-shielded irradiator licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in 10 CFR 30.35 must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where irradiators are used or stored and to leaking sources. Licensees must transfer these records important to decommissioning either to the new licensee before licensed activities are transferred or assigned according to 10 CFR 30.34(b) or to the appropriate NRC regional office before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most self-shielded irradiator applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 10 CFR 30.35. The limits for typical self-shielded irradiator sealed sources are shown in Table 8.1. Applicants requesting more than one radionuclide need to use the sum of the ratios method to determine whether financial assurance is needed. See Appendix F for additional information.

Table 8.1 Minimum Inventory Quantity Requiring Financial Assurance

RADIONUCLIDE	ACTIVITY	
	Gigabecquerels	Curies
Cs-137	3.7×10^6	100,000
Co-60	3.7×10^5	10,000
Sr-90	3.7×10^4	1,000

In most cases, a licensee would need to possess several irradiators before the financial assurance requirements would apply. Since the standard self-shielded irradiator license does not specify the maximum number of irradiators that a licensee may possess (allowing flexibility in obtaining additional irradiators specifically authorized by the license without amending its license), it contains a condition requiring the licensee to limit its possession of self-shielded irradiators to quantities not requiring financial assurance for decommissioning.

Applicants and licensees wanting to possess self-shielded irradiators or irradiators and other licensed materials exceeding the limits in 10 CFR 30.35 must submit evidence of financial assurance or a decommissioning funding plan (10 CFR 30.35 (b)). Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds except for the Statement of Intent for government licensees. See Appendix F for the recommended wording for a Statement of Intent.

NRC will authorize possession exceeding the limits shown in Table 8.1 without requiring decommissioning financial assurance, for the purpose of normal source exchange for no more than 30 days.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All self-shielded irradiator licensees need to maintain records of structures and equipment where each irradiator was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees may substitute appropriate records (e.g., a sketch of the room or building, or a description of the area) concerning the specific areas and locations. In addition, if self-shielded irradiator licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For self-shielded irradiator licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each irradiator was used or stored.

Response from Applicant: No response is needed from most applicants. If financial assurance is required, submit evidence as described in RG 3.66.

Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned according to 10 CFR 30.34(b) or to the appropriate NRC regional office before the license is terminated.

References: See the Notice of Availability (on the inside front cover of this draft report) to obtain copies of Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, and Policy and Guidance Directive FC 90-2 (Rev. 1), "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

8.7 Item 6: Purpose(s) for which Licensed Material will be Used

Regulations: 10 CFR 30.33(a)(1).

Criteria: Proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and irradiators will be used only for the purposes for which they were designed and according to the manufacturer's recommendations and instructions for use as specified in an approved SSD Registration Certificate. Uses other than those already listed must not compromise the integrity of the source or source shielding or other components of the device critical to radiation safety.

Discussion: Allowed uses normally include irradiation of blood, insects, animals, biological samples, and inanimate objects. Usually prohibited are irradiation of flammable and explosive materials which may harm the shielding or the sealed source containment, or other materials (e.g., unsealed containers of acids or corrosive liquids) which may interfere with the safe operation of the device. Irradiation of food for commercial distribution to the public is subject to regulations of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) and will not be discussed in this document.

Requests to irradiate items not listed or prohibited in the SSD Registration Certificate will be reviewed on a case-by-case basis. Applicants need to submit enough information to demonstrate that irradiation of the proposed items will not compromise the integrity of the source or source shielding, or other components critical to radiation safety of the device. Contact the appropriate NRC Regional Office (see [Figure 2.1](#)) for additional case-specific guidance. Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., FDA and USDA regulations about irradiation of food for commercial distribution).

Response from Applicant: If the self-shielded irradiator will be used for the purposes listed on the SSD Registration Certificate, state the following: "The self-shielded irradiator(s) will be used for the purposes described in their respective SSD Registration Certificates." If the self-shielded irradiator will be used for purposes other than those listed on the SSD Registration Certificate, specify these purposes and submit safety analyses (and procedures, if needed) to support safe use.

8.8 Item 7: Individual(s) Responsible for Radiation Safety Program and their Training

Experience - Radiation Safety Officer (RSO)

Regulations: 10 CFR 30.33(a)(3).

Criteria: RSOs must have adequate training and experience. Successful completion of training as described in Appendix G is evidence of adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the Radiation Safety Officer, or RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner.

[Figure 8.1 RSO Responsibilities. Typical duties and responsibilities of RSOs.](#)

Typical RSO duties are illustrated in [Figure 8.1](#) and described in Appendix H. NRC requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

Response from Applicant: Provide the following:

- Name of the proposed RSO.

AND EITHER:

- Statement that: "Before obtaining licensed materials, the proposed RSO will have successfully completed training described in Appendix G in draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated October 1997";

AND

- Statement that: "Before being named as the RSO, future RSOs will have successfully completed training described in Appendix G in draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated October 1997. Within 30 days of naming a new RSO, we will submit the new RSO's name to NRC to include in our license."

OR

- Alternative information demonstrating that the proposed RSO is qualified by training and experience.

Note:

- It is important to notify NRC, as soon as possible, of changes in the designation of the RSO; such notifications will be handled as administrative amendments not requiring fees as long as the application contains the commitment listed in the third bullet under "Response from Applicant."
- Alternative responses will be reviewed using the criteria listed above.

8.9 Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Workers)

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33.

Criteria: Individuals working with, as well as in the vicinity of, a self-shielded irradiator must have adequate training and experience. For individuals working with irradiators, also known as authorized users, successful completion of training as described in Appendix G is evidence of adequate training and experience. For those individuals who are not authorized users yet work in the vicinity of a self-shielded irradiator and, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 mSv (100 mrem), the licensee must provide training as required by 10 CFR 19.12.

Discussion: Authorized users must ensure the proper use, security, and routine maintenance of self-shielded irradiators containing licensed material. They must have appropriate training to provide reasonable assurance that they will use the irradiator safely, maintain security of and access to the irradiator, and respond appropriately to accidents and malfunctions.

Individuals other than authorized users may perform routine maintenance on irradiators. However, if they have not received training as an authorized user, they must work under the supervision and in the direct physical presence of someone who has.

Some licensees may have specific individuals trained to perform installations, relocations, non-routine maintenance, or repairs. Authorizations for these functions are separate from those for an authorized user or an individual who performs routine maintenance and

will be specifically stated in a license condition. Appendix I contains suggested training for individuals who will conduct non-routine maintenance.

Authorized users, individuals performing routine maintenance, and individuals performing installations, relocations, non-routine maintenance, or repairs would be most likely to receive doses in excess of 1 mSv (100 mrem) in a year. However, potential radiation doses received by any individual working in or frequenting restricted areas must also be evaluated. All individuals working with or around licensed materials should receive training commensurate with their assigned duties, and if it is likely they could receive doses over 1 mSv (100 mrem) in a year, they must receive instruction as specified by 10 CFR 19.12. For example, a licensee could determine that housekeeping staff, while not likely to receive doses over 1 mSv (100 mrem), need to be informed of the nature of the irradiator and the meaning of the radiation symbol, and need to be instructed not to touch the irradiator and to remain out of the room if the irradiator door is open.

Response from Applicant: Provide either of the following:

- The statement: "Before using licensed material, authorized users will receive the training described in Appendix G in draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-shielded Irradiator Licenses,' dated October 1997";

OR

- A description of the training and experience for proposed authorized users.

Note: Alternative responses will be evaluated using the criteria listed above.

8.10 Item 9: Facilities and Equipment

Regulations: 10 CFR 30.33(a)(2).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Self-shielded irradiators incorporate many engineering features to protect individuals from unnecessary radiation exposure. These devices are usually designed for use in a laboratory environment, i.e., inside a building, protected from the weather, and without wide variations of temperature and humidity. For information to help applicants determine the location of irradiators, see the sections on the SSD Registration Certificate entitled, "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use."

For example, if a proposed location for a self-shielded irradiator is not within the conditions of normal use or the limitations of use, the applicant will need to provide adequate justification. In addition, the applicant will need to take compensatory measures (e.g., increased surveillance and maintenance) to ensure that the irradiator operates as designed and provides the intended level of protection. IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training," dated June 11, 1996, discusses an incident resulting from irradiator failure in which the lack of a climate-controlled environment (i.e., loading dock) may have accelerated the degradation of internal components leading to a failed interlock and excessive dose received by an irradiator operator.

Self-shielded irradiators vary in weight from several hundred to several thousand kilograms (pounds). Before installing an irradiator, licensees need to evaluate whether the floor in the proposed location can support the irradiator. Often licensees locate self-shielded irradiators on a ground floor. Some smaller and lighter irradiators require additional security measures to prevent unauthorized removal (e.g., locked in a room, bolted to the floor). For more information see "Radiation Safety Program - Operating and Emergency Procedures" and "Radiation Safety Program - Public Dose."

The fire-resistant properties of most irradiators should provide adequate radioactive material containment and shielding integrity in most situations; however, additional protection is desirable for some situations. For example, the room housing the irradiator should be equipped with an automatically-operated fire detection and control system (sprinkler, chemical, or gas). As an alternative, the self-shielded irradiator should be located under conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls (e.g., coordination with and training of fire-fighting personnel) that ensure a low level of radiation risk attributable to fires.

Response from Applicant: Provide either of the following:

- The statement: "We will ensure that each area where a self-shielded irradiator is located corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other Considerations of Use' on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; *and* each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area

and other controls ensure a low-level radiation risk attributable to fires."

OR

- Submit alternative information; be sure to include justification for placing an irradiator in an area that does not correspond to the "Conditions of Normal Use" and the "Limitations and/or Other Considerations of Use."

Note: Alternative information will be reviewed using the criteria listed above.

References: See the Notice of Availability (on the inside front cover of this draft report) to obtain a copy of IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training," dated June 11, 1996.

8.11 Item 10: Radiation Safety Program - Audit Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2102.

Criteria: Licensees must review the content and implementation of their radiation protection programs annually to ensure the following:

- Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are as low as reasonably achievable (ALARA) (10 CFR 20.1101); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Appendix J contains a suggested audit program that is specific to the use of self-shielded irradiators and is acceptable to NRC. All areas indicated in Appendix J may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit need not be reviewed at the next audit. Generally, audits are conducted at least once every 12 months.

Currently the NRC's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of irradiator users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. The NRC will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the NRC can exercise discretion and may elect not to cite a violation. The NRC's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies. For additional information on NRC's use of discretion on issuing a notice of violation, refer to "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600, dated June 1995).

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow up.

Response From Applicant: The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase.

References: See the Notice of Availability (on the inside front cover of this draft report) to obtain copies of: Manual Chapter 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes," NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions," dated June 1995, and IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996. NUREG-1600 is also available on the Internet. Visit NRC's Home Page (<http://www.nrc.gov/>), choose "Nuclear Materials," then "Enforcement," "Enforcement Guidance Documents," and then "Enforcement Policy."

8.12 Item 10: Radiation Safety Program - Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2).

Criteria: Licensees must possess, or have access to, radiation monitoring instruments which are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: All licensees possessing self-shielded irradiators should have, or have access to, calibrated radiation detection instruments to determine radiation levels in areas adjacent to the irradiator. Usually it is not necessary for a licensee to have a survey meter solely for use during irradiator operations since it is not expected that a survey be performed each time a sample is irradiated. In these cases it is

acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

However, as explained in an "Urgent Notice" with an enclosed Order, both dated July 3, 1984 (see Appendix E), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism which would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses which authorize J. L. Shepherd Mark I or Model 81-22 irradiators and requires licensee to provide either a calibrated and operable radiation survey meter or room monitor for use with either of these irradiators. Although not required for all licensees possessing moving-source irradiators, it would be prudent for these licensees to use either a calibrated survey meter or room monitor to ensure that the sources are in the shielded position whenever a sample is not undergoing irradiation.

The NRC requires that survey meter calibrations be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See Appendix K for more information.

Response from Applicant: Provide one of the following:

- A statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated October 1997. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used."

OR

- A statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated October 1997. Additionally, we will implement the model survey meter calibration program published in Appendix K to draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated October 1997, and we will ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used."

OR

- A description of alternative equipment and/or procedures for ensuring that interlocks function, as required, to return moving self-shielded irradiator sources to the shielded position and/or determining source shielding integrity after an incident involving the self-shielded irradiator.

Note:

- Alternative responses will be reviewed using the criteria listed above.
- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in Appendix E. Applicants requesting these irradiators must ensure that their radiation detection instruments meet these requirements.
- Applicants who plan to perform non-routine maintenance that will affect safety-critical components (e.g., sealed source, radiation shielding, source movement control or mechanism, interlocks) will need to possess and use appropriate, calibrated radiation survey meters. Refer to the section on "Radiation Safety Program - Maintenance," Appendix I, and Appendix K for more information.
- Required calibration records must be retained for a minimum of 3 years.

8.13 Item 10: Radiation Safety Program - Material Receipt and Accountability

Regulations: 10 CFR 30.34(e), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201, 10 CFR 30.35(g)(2).

Criteria: Licensees must do the following:

- Maintain accountability for self-shielded irradiators by conducting physical inventories at intervals not to exceed 6 months (or as justified by the applicant) to account for all sealed sources.
- Maintain records of receipt, transfer, and disposal of self-shielded irradiators.

Discussion: While loss, theft, or misplacement of most self-shielded irradiators is unlikely because of their size and weight, accountability for licensed materials must be ensured; see [Figure 8.2](#). Many licensees record use of self-shielded irradiators in a log book. Licensees are also required to conduct leak tests of irradiator sealed source(s) at the frequency specified in the SSD Registration Certificate. Since both of these activities require that an individual approach the irradiator, records of use and leak tests may be used as

part of an accountability program. For more information, see "Radiation Safety Program - Operating and Emergency Procedures" and "Radiation Safety Program - Leak Tests" in this draft report. However, since some irradiators may not be in use or are used rarely, NRC expects licensees to physically approach and account for all sealed sources at least every 6 months.

Figure 8.2 Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories.

Receipt, transfer, and disposal records must be maintained for the times specified in Table 8.2. Typically, these records contain the following types of information:

- Radionuclide and activity (in units of becquerels or curies) of byproduct material in each sealed source;
- Manufacturer's name, model number, and serial number (if appropriate) of each device containing byproduct material;
- Location of each sealed source; and device
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number).

Information on locations where irradiators are used or stored are records important to decommissioning and required by 10 CFR 30.35(g)(2).

Table 8.2 Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until NRC terminates the license
Important to decommissioning	Until the site is released for unrestricted use

Response from Applicant: Provide either of the following:

- A statement that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources

and devices received and possessed under the license."

OR

- A description of procedures for ensuring that no self-shielded irradiator has been lost, stolen, or misplaced and how often this will be done

Note: Alternative responses will be evaluated using the criteria listed above.

8.14 Item 10: Radiation Safety Program - Occupational Dosimetry

Regulations: 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1207, 10 CFR 20.1208.

Criteria: Applicants must do either of the following:

- Maintain, for inspection by NRC, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits as shown in [Figure 8.3](#).

OR

- Provide dosimetry as follows:
 - Personnel dosimeters which are processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor and are exchanged at a frequency recommended by the processor; or
 - Direct or indirect reading pocket ionization chambers that:
 - Are assigned to a single individual whose accumulated dose is read, recorded, and the chamber recharged, as appropriate, before the chamber is assigned to another individual;
 - Have a range of 0 to at least 2 mSv (200 mrem);
 - Are checked at intervals not to exceed one year for correct response to radiation;
 - Read within $\pm 20\%$ of the true radiation exposure; and
 - Are used under a program that prescribes action to evaluate the individual's dose.

Figure 8.3 Annual Dose Limits for Radiation Workers.

Discussion: Under conditions of routine use and maintenance, the typical self-shielded irradiator user does not require a personnel monitoring device (dosimetry). Appendix L provides guidance on preparing a written evaluation demonstrating that self-shielded irradiator users are not likely to exceed 10 percent of the applicable limits and thus, are not required to have personnel dosimetry.

When personnel monitoring is needed, most licensees use either film badges or thermoluminescent dosimeters (TLDs) that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The exchange frequency for TLDs is usually quarterly. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the criteria above are met. See ANSI N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," for more information.

Response from Applicant: Provide either of the following:

- A statement that: "Either we will maintain, for inspection by NRC, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the Criteria in the section entitled 'Radiation Safety Program - Occupational Dosimetry' in draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated October 1997."

OR

- A description of an alternative method for demonstrating compliance with the referenced regulations.

Note:

- Alternative responses will be evaluated using the criteria listed above.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with NRC requirements (e.g., to respond to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available for purchase from GPO and on the Internet at the following address: <http://ts.nist.gov/ts/htdocs/210/214/dosim.htm>. Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically at the following address: <http://www.ansi.org/>.

8.15 Item 10: Radiation Safety Program - Public Dose

Regulations: 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1003, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107.

Criteria: Licensees must do the following:

- Ensure that licensed self-shielded irradiators will be used, transported, and stored in such a way that members of the public will not receive more than 1 millisievert (mSv) [100 millirem (mrem)] in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.
- Control and maintain constant surveillance over self-shielded irradiators that are not in storage and secure stored self-shielded irradiators from unauthorized access, removal, or use.

Discussion: Members of the public include persons who work or may be near locations where self-shielded irradiators are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

[Figure 8.4 Proper Location of Irradiator. Irradiators should be located away from occupied areas and secured to prevent authorized use or removal.](#)

Security procedures described in "Facilities and Equipment" and "Radiation Safety Program - Operating and Emergency Procedures" should be effective in limiting the exposure to the public during use or storage. See [Figure 8.4](#). Public dose is controlled, in part, by ensuring that irradiators are secure (e.g., located in a locked area) to prevent unauthorized access or use. As shown in [Figure 1.1](#), most self-shielded irradiators are massive [i.e., hundreds of kilograms (pounds) and the size of file cabinets], not likely to be easily removed from their intended location, and may not need to be in a locked area to prevent loss, theft, or unauthorized relocation.

However, smaller units such as those used to calibrate TLDs are more easily moved and should be located in a locked area or be bolted in place. Irradiator use is usually restricted by controlling access to the keys needed to operate the irradiator and/or to keys to the locked

irradiator area. Only authorized users should have access to these keys.

Public dose is also affected by the choice of storage and use locations and conditions. Since a self-shielded irradiator presents a radiation field, it must be located so that the radiation level in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time spent near an irradiator, increasing the distance from the irradiator, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to the irradiator location either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the manufacturer, the "inverse square" law to evaluate the effect of distance on radiation levels, occupancy factor to account for the actual presence of the member of the public, and limits on the use of self-shielded irradiator(s). See Appendix M for an example.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the location of irradiators, changes the type or frequency of irradiator use, adds self-shielded irradiators, changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix M for examples of methods to demonstrate compliance.

Response from Applicant: No response is required from the applicant in a license application, but this matter will be examined during inspection.

8.16 Item 10: Radiation Safety Program - Operating and Emergency Procedures

Regulations: 10 CFR 30.34(e), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2203, 10 CFR 30.50, 10 CFR 21.21, 10 CFR 19.11(a)(3).

Criteria: Before using an irradiator, licensees must do the following:

- Develop, implement, and maintain model-specific operating and emergency procedures containing the following elements:

- An analysis of each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine if any special safety procedures are needed;
- Instructions for using the self-shielded irradiator and performing routine maintenance, according to the manufacturer's written recommendations and instructions;
- Instructions for maintaining security to prevent unauthorized use, access, or removal of self-shielded irradiators and the associated sealed sources;
- Steps to take to keep radiation exposures ALARA;
- Steps to maintain accountability;
- Steps to control access to a malfunctioning or damaged irradiator;
- Steps to take, and whom to contact (e.g., RSO, local officials), when an irradiator malfunctions or has been damaged.

AND

- Provide copies of operating and emergency procedures to all users ;
- Maintain a current copy of operating and emergency procedures at each irradiator's control panel (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

Discussion: When used as designed, properly functioning self-shielded irradiators pose little radiation safety risk. However, improper maintenance, irradiating material incompatible with an irradiator's design, or operating an irradiator in an environment other than that recommended by the manufacturer, could lead to damage or malfunction of an irradiator and elevated exposure rates in the irradiator's immediate vicinity. Operating and emergency procedures should be developed to minimize these risks, while keeping radiation exposures ALARA. These procedures must be model-specific to account for potentially significant differences in irradiator design and construction that lead to manufacturers providing different instructions and recommendations for operating and maintaining irradiators.

Sources contained in many self-shielded irradiators are designed to deliver significant doses in short periods of time. Although self-shielded irradiators are safe when used correctly, unauthorized access to the irradiator or the irradiator's sources by untrained individuals could lead to a life-threatening situation. Therefore, operating procedures will also need to address access control and accountability. Many licensees achieve access control by permitting only authorized users or the RSO to have access to the keys for the irradiator and/or the irradiator area. Accountability of an operating irradiator may be ensured by using a log book to record irradiator use, maintenance, service calls, and sealed source leak tests. Each activity requires an individual to interact in some way with the irradiator and thereby verify its presence. For sources contained in irradiators that are not actively used, licensees would need to find other methods to maintain accountability, such as conducting inventories.

Licensees must post current copies of the operating procedures applicable to licensed activities (e.g., at the irradiator control panel). If posting of a document is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

[Figure 8.5 Proper Handling of Incident. Licensee personnel implement emergency procedures when a flammable sample catches fire.](#)

[Figure 8.5](#) illustrates proper response to a fire in an irradiator. Emergency procedures should be developed to address a spectrum of incidents (e.g., interlock failure, flood, earthquake). Emergency response procedures should contain the following elements:

- Leave the irradiator room to reduce radiation exposure;
- Control access (e.g., lock door);
- Contact the individual responsible for the irradiator program for further instructions and to initiate emergency response. (Telephone numbers for the responsible individual, the irradiator manufacturer or representative, fire department, or other emergency response organization, and the NRC should be posted or easily accessible.);
- Survey areas outside the irradiator room to determine whether further restriction of the area is necessary to ensure that no one can enter the area if the radiation level exceeds 0.02 mSv (2 mrem) per hour; and
- As appropriate, require timely reporting to NRC according to 10 CFR 20.2201-20.2203, 10 CFR 30.50, and 10 CFR 21.21.

The NRC must be notified when a self-shielded irradiator is lost, stolen, or other conditions occur. The RSO must be proactive in evaluating whether NRC notification is required. Refer to the regulations (10 CFR 20.2201-20.2203, 10 CFR 30.50, and 10 CFR 21.21) for a description of when and where notifications are required.

Appendix N provides information for applicants to consider when developing their procedures for self-shielded irradiators.

Response from Applicant: Do either of the following:

- State: "Operating and emergency procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled 'Radiation Safety Program - Operating and Emergency Procedures' in draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated October 1997."

OR

Submit alternative procedures.

Note:

- Alternative procedures will be reviewed using the criteria listed above.
- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in Appendix E. Applicants requesting these irradiators must ensure that their operating and emergency procedures address these requirements.
- Before using a new model irradiator, licensees need to revise operating and emergency procedures to include procedures specific to the new irradiator.

8.17 Item 10: Radiation Safety Program - Leak Tests

Regulations: 10 CFR 30.53, 10 CFR 20.1501, 10 CFR 20.2103.

Criteria: NRC requires testing to determine whether there is any radioactive leakage from the source in the self-shielded irradiator. Records of test results must be maintained.

Discussion: When issued, a license will require performance of leak tests at intervals approved by the NRC or an Agreement State and specified in the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (0.005 microcurie) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the self-shielded irradiator manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Response from Applicant: Do one of the following:

- State: "Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source

and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the self-shielded irradiator manufacturer's and kit supplier's instructions."

OR

State: "Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the self-shielded irradiator manufacturer's and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix O to draft NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Information about Self-Shielded Irradiators,' dated October 1997."

OR

- A description of alternative equipment and/or procedures for determining whether there is radioactive leakage from sources contained in self-shielded irradiators.

Note:

- Alternative responses will be reviewed using the criteria listed above.
- If a self-shielded irradiator is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the irradiator according to the procedures previously approved on its license.

References: See the Notice of Availability (on the inside front cover of this draft report) to obtain a copy of Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

8.18 Item 10: Radiation Safety Program - Maintenance

Regulations: 10 CFR 20.1101, 10 CFR 30.34(e).

Criteria: Licensees must routinely maintain self-shielded irradiators according to the manufacturer's written recommendations and instructions; see [Figure 8.6](#). For self-shielded irradiators, radiation safety procedures for routine maintenance must consider ALARA and ensure that the irradiator functions as designed and source integrity is not compromised.

In this draft report, "non-routine maintenance" means any repair, removal, replacement, or alteration involving: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, any component that may affect safe operation of the irradiator, or any other activities during which personnel could receive radiation doses exceeding NRC limits.

Non-routine maintenance must be performed by the self-shielded irradiator manufacturer or a person specifically authorized by NRC or an Agreement State; see [Figure 8.7](#). Requests for specific authorization to perform non-routine maintenance (see Appendix I) must demonstrate that personnel performing the work do the following:

- Have adequate training and experience;
- Use equipment and procedures that ensure compliance with regulatory requirements, and consider ALARA; and
- Ensure that the self-shielded irradiator functions as designed and that source integrity is not compromised.

Discussion: NRC IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators because of Inadequate Maintenance and Training," dated June 11, 1996, describes two incidents in which safety interlocks on self-shielded irradiators failed to prevent inadvertent exposure.

[Figure 8.6 Routine Maintenance and Lubrication. To ensure proper operation of the unit, self-shielded irradiator licensees need to perform routine maintenance according to the manufacturer's written instructions and recommendations.](#)

NRC permits self-shielded irradiator licensees to perform routine maintenance of the irradiator provided they follow the self-shielded irradiator manufacturer's written recommendations and instructions. Although manufacturers may use different terms, "routine maintenance" includes, but is not limited to, cleaning, lubrication, changing batteries, relays or fuses. Routine maintenance does *not* include any activities that involve the source, source drive mechanism, or removing the shielding or source and any other activities during which personnel could receive radiation doses exceeding NRC limits.

Figure 8.7 Non-Routine Maintenance. For non-routine maintenance, most licensees rely on the manufacturer or other service companies.

The NRC license will require that non-routine maintenance (as defined above) be performed only by the manufacturer or other persons specifically licensed by the Commission or an Agreement State to perform such services. Most licensees do not perform non-routine maintenance because they must have specialized equipment and technical expertise to perform these activities. Applicants seeking authorization to perform non-routine maintenance must submit specific procedures for review. See Appendix I for more information.

Response from Applicant:

Routine Maintenance: Submit either of the following:

- A statement that: "We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer's written recommendations and instructions."

OR

- Alternative procedures for NRC's review.

Non-Routine Maintenance: Submit either of the following:

- A statement that: "We will have the self-shielded irradiator manufacturer or other person authorized by NRC or an Agreement State perform non-routine maintenance."

OR

- The information listed in Appendix I supporting a request for authorization to perform this work.

Note:

- Alternative procedures for performing routine maintenance will be reviewed using the criteria listed above.
- Information requested in Appendix I will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine maintenance.

References: See the Notice of Availability (on the inside front cover of this draft report) to obtain a copy of NRC IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators because of Inadequate Maintenance and Training," dated June 11, 1996.

8.19 Item 10: Radiation Safety Program - Transportation

Regulations: 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.37, 10 CFR 71.38, Subpart H of 10 CFR Part 71, 49 CFR Parts 171-178, 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51.

Criteria: Applicants must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: The general license in 10 CFR 71.12 provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Most self-shielded irradiators contain quantities of radioactive material that require using a Type B package. Before offering a Type B package for shipment, the licensee needs to be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the 10 CFR 71.12 general license. For information about QA plans, see Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986. For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Spent Fuel Project Office (SFPO) by calling NRC's toll-free number 800-368-5642 and asking for extension 415-8500. For information about associated fees, contact NRC's Office of the Chief Financial Officer by calling NRC's toll-free number 800-368-5642 and asking for extension 415-7554.

Some irradiator licensees who rarely ship radioactive material have chosen to transfer possession of radioactive materials to an irradiator manufacturer (or service licensee) with an NRC or Agreement State license who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the irradiator at temporary job sites (e.g., at the irradiator location);
- Actually takes possession of the irradiator under its license;
- Uses an approved Type B package;
- Is registered with NRC as a user of the Type B package; and

- Has an NRC-approved QA plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements applicable to irradiator licensees. Part 1 of Appendix P lists major DOT regulations and Part 2 contains a sample bill of lading.

Before the adoption of the requirements of 10 CFR Part 71 in 1966, self-shielded irradiators could be transported without being evaluated under the hypothetical accident conditions that are now incorporated in 10 CFR Part 71. Because pre-1966 irradiators are not certified shipping packages, transporting them may require transferring the sealed source from the irradiator to a certified Type B package or using a certified package for the irradiator containing the sealed sources. Only if these options are not viable will NRC consider a licensee's request for an exemption for a one-time shipment according to 10 CFR 71.8. Exemption requests should contain the information described in Part 3 of Appendix P. In addition to an NRC exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before offering a Type B package for shipment, a licensee needs to have registered with NRC as a user of the package and obtained NRC's approval of its QA program. Transportation issues will be reviewed during inspection.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1983 revision)" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. See the Notice of Availability (on the inside front cover of this draft report) to obtain a copy of the Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979, and Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986.

8.20 Item 10: Radiation Safety Program - Minimization of Contamination

Regulations: 10 CFR 20.1406.

Criteria: Applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. Irradiator applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment," "Radiation Safety Program - Operating and Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Self-Shielded Irradiator Transfer and Disposal."

8.21 Item 11: Waste Management - Self-Shielded Irradiator Disposal and Transfer

Regulations: 10 CFR 20.2001, 10 CFR 30.41, 10 CFR 30.51.

Criteria: Licensed materials must be disposed of according to NRC requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: When disposing of self-shielded irradiators, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer of the irradiator, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the

methods described in 10 CFR 30.41. In addition, all packages containing radioactive sources must be prepared and shipped according to NRC and DOT regulations. Records of the transfer must be maintained as required by 10 CFR 30.51.

Licensees should promptly dispose of unused irradiators to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Response from Applicant: The applicant does not need to provide a response to this item during the licensing phase. However, the licensee should establish and include waste disposal procedures in its radiation safety program.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

The next two items on [NRC Form 313](#) are to be completed on the form itself.

8.22 Item 12: Fees

On [NRC Form 313](#), enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

8.23 Item 13: Certification

Individuals acting in a private capacity are required to date and sign [NRC Form 313](#). Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. *Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant.* As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. *NRC will return all unsigned applications for proper signature.*

Note:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

9 Amendments and Renewals to a License

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request.
- Submit in duplicate, either an [NRC Form 313](#) or a letter requesting amendment or renewal.
- Provide the license number.
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or radiation protection program. As an alternative, describe clearly the exact nature of the changes, additions, and deletions.

Using the suggested wording of responses and committing to using the model procedures in this draft report will expedite NRC's review.
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10 Termination of Activities

Regulations: 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d) and (j), 10 CFR 30.51(f).

Criteria: The licensee must do the following:

- Notify NRC, in writing, within 60 days, when its license has expired or a decision has been made to permanently cease licensed activities at the entire site regardless of contamination levels.

- Notify NRC, in writing, within 60 days, when principal activities have not been conducted for 24 months or a decision has been made to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to NRC requirements.
- Certify the disposition of licensed materials by submission of [NRC Form 314](#), "Certificate of Disposition of Materials" or equivalent information.
- Before a license is terminated, send the records important to decommissioning (as required by 10 CFR 30.35(g)) to the appropriate NRC regional office. If licensed activities are transferred or assigned according to 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: Licensees are not required to notify NRC when principal activities have not been conducted for 24 months or a decision has been made to permanently cease licensed activities in any separate building or outdoor area, unless the separate building or outdoor area contains residual radioactivity making it unsuitable for release according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

For guidance on the disposition of licensed material, see the section on "Waste Management - Self-Shielded Irradiator Disposal or Transfer." For guidance on decommissioning records, see the section on "Radioactive Materials - Financial Assurance and Record Keeping for Decommissioning."

Licensees should promptly dispose of unused irradiators to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. However, when the license expires or at the time the licensee ceases operations, then the applicant must perform decommissioning activities and submit [NRC Form 314](#) or equivalent information.

References: Copies of [NRC Form 314](#), "Certificate of Disposition of Materials," are available upon request from NRC's Regional or Field Offices; see [Figure 2.1](#).

Appendix A: List of Documents Considered in the Preparation of this Draft NUREG Report List of Documents Considered in the Preparation of this Draft NUREG Report

This draft report incorporates and updates the guidance previously found in the Regulatory Guides (RG), Policy and Guidance Directives (P&GD), Information Notices (IN), and Technical Assistance Requests (TAR) listed in Table A.1. When this draft report is issued in final form, the documents in Table A.1 will be considered superseded and should not be used.

Table A.1 List of Documents Considered in the Preparation of this Draft Report

Document Identification	Title	Date
RG 10.9	Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators, Rev. 1	12/88
P&GD FC 84-16	Standard Review Plan for Applications for Licenses for the Use of Self-Contained Source-Storage Irradiators, Rev. 1	10/84
P&GD FC 84-18	Transportation of Irradiator License Units Not Meeting Current Requirements of 10 CFR Part 71	11/84
IN 96-35	Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training	6/11/96
TAR	University of Pittsburgh	1/17/91
TAR	University of Wisconsin and Maintenance of J. L. Shepherd Mark I Irradiators	8/8/94

Appendix B: United States Nuclear Regulatory Commission Form 313

GIF FILE	TIF FILE
Form 313	Form 313

Appendix C: Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313

ITEMS 5 & 6: Materials to be Possessed and Proposed Uses

[ITEMS 5 & 6: Materials to be Possessed and Proposed Uses](#)

ITEMS 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal

[ITEMS 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal](#)

Appendix D: Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. The new name of the licensed organization. If there is no change, the licensee should so state.

2. The new licensee contact and telephone number(s) to facilitate communications.
3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
4. An indication of whether the transferor will remain in non-licensed business without the license.
5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.
8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.
9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.
10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d); public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the NRC for license terminations.
11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?
12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35, 40.36, and 70.25. Include information about how the transferee and transferor propose to divide the transferor's assets, and

responsibility for any cleanup needed at the time of transfer.

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 10 CFR 30.35(g); implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with NRC before license transfer.

14. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.
15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

Appendix E: J. L. Shepherd Order

J. L. Shepherd Order

July 3, 1984

UNITED STATES

NUCLEAR REGULATORY COMMISSION

URGENT NOTICE

TO ALL LICENSEES WHO POSSESS J. L. SHEPHERD IRRADIATORS

An NRC licensee recently identified a malfunction in the lock mechanism of its J. L. Shepherd self-shielded irradiator which could have resulted in a radiation overexposure. Although no overexposure appears to have occurred, the potential hazard warrants immediate preventive action. Therefore, we have prepared the enclosed Order which requires the use of radiation survey equipment when the irradiators are being used.

If you possess a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator, do not use it unless you provide appropriate radiation monitoring as specified in the Order. If you do not currently possess the appropriate equipment, you must obtain it before you resume use of your irradiator. Also, you should report any problems to your nearest NRC regional office immediately. Do not attempt to repair an irradiator, or allow anyone else to attempt repairs, unless specific authorization for repair of the irradiator which you possess is provided in an NRC license.

We suggest that you review who has access to your irradiator, and establish strict controls to assure that no untrained personnel have access. Trained persons who continue to use the irradiator should conduct careful radiation surveys as specified in the Order. Irradiator doors should be opened slowly, to minimize any accidental exposure and to avoid "blanking out" of instruments due to high exposure rates. Any unusual meter reading should be taken as evidence of a problem.

We are including in this mailing certain licensees about which we are uncertain whether they possess J. L. Shepherd irradiators. If you do not possess a J. L. Shepherd irradiator, please disregard this notice.

Because this Order is effective immediately, it is important that you notify your radiation safety personnel immediately, and retain this Order with your license records. Questions and comments may be directed to your nearest NRC regional office.

Sincerely,

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Enclosure: Order Modifying License

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D. C. 20555

ORDER MODIFYING CERTAIN LICENSES (EFFECTIVE IMMEDIATELY)

I

Recently, the Nuclear Regulatory Commission (NRC) staff was notified by a licensee of the failure of a locking mechanism on a self-shielded irradiator which could have resulted in a radiation overexposure. ("Self-shielded" irradiators are designed so that the radioactive source remains in a shielded position at all times, both during storage and during irradiations. Therefore, the irradiators need not be placed in a shielded room.)

The irradiator is a J. L. Shepherd Mark I, containing about 6,000 curies of cesium 137. The unit is operated as follows: (1) With the source in its shielded storage position, the shielded door is opened, (2) materials to be irradiated are placed inside the irradiator chamber, (3) the shielded door is closed, (4) the radioactive source is raised into the irradiation chamber, (5) after irradiation is complete, the source is lowered, and (6) the door is opened for removal of irradiated materials.

The shielded door is interlocked so that it should not open when the radioactive source is in the irradiation chamber. However, in the case reported to NRC, the lock mechanism failed. In such a situation, an operator who opens the shielded door with the source raised could be subjected to substantial radiation exposure. The J. L. Shepherd Model 81-22 irradiator employs an interlock similar to the Mark I.

The NRC staff has examined the irradiator in question and confirmed the defect. Furthermore, a New York City inspector checking a J. L. Shepherd Mark I irradiator in New York reported a malfunctioning interlock system. NRC and the Agreement States are studying the problem further to assess its generic implications

Based on the foregoing, I have concluded that the possibility of failure of locking mechanisms and/or mechanical timers on J. L. Shepherd Mark I and Model 81-22 irradiators represents a potential radiation hazard warranting immediate preventive action pending further investigation. I have determined, therefore, that the public health, safety, and interest require that the restrictions on the use of

such irradiators as prescribed in Section II of this Order should be made immediately effective.

II

Accordingly, pursuant to Sections 81, 116 I, 162 o, and 182 of the Atomic Energy Act of 1954, as amended, and 10 CFR Parts 2 and 30 of the Commission's regulations, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

Each license that authorizes possession of byproduct material in a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator is hereby amended to add the following conditions:

1. The J. L. Shepherd irradiator shall not be used unless the licensee provides a calibrated and operable radiation survey meter or room monitor for use with the irradiator.
2. The irradiator door shall not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
3. Each room monitor (a) shall be operable at all times when the irradiator is in use, (b) shall activate a visible and audible alarm when radiation levels exceed 2 millirems per hour, (c) shall be located to detect any radiation escaping from the irradiator door, and (d) shall be located so that it is visible to the irradiator user when he is next to the irradiator.
4. If a room monitor is not installed, a survey meter shall be used (a) to determine the radiation level at the irradiator door when the door is closed, and (b) to check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators shall position themselves so as to minimize exposure to any radiation escaping from the open door.
5. If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee shall stop use of the irradiator and immediately notify the appropriate NRC regional office by telephone.
6. The licensee shall not attempt repair or authorize others to attempt repair of the irradiator except as specifically authorized in a license issued by NRC.

III

Any affected licensee may request a hearing on this Order. A request for a hearing shall be submitted within twenty (20) days of the date

of this Order to Mr. R. E. Cunningham, Director, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Executive Legal Director, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. ANY REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.IV

If a hearing is requested, the Commission will issue an Order designating the time and place of any such hearing. If a hearing is held the issue to be considered at such a hearing will be: Whether, on the basis of the matters set forth in Section 1 and II of this Order, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

Dated at Bethesda, Maryland this 3rd day of July, 1984

Appendix F: Guidance on Financial Assurance

Determining Need for Financial Assurance

If the only radioactive materials possessed are sealed sources in self-shielded irradiators, use Table F.1 to determine if financial assurance is required.

Table F.1 Worksheet for Determining Need for Financial Assurance for Self-Shielded Irradiators

Step No.	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies ⁽³⁾			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000

3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

If the sum of the fractions is greater than or equal to 1, the applicant will need to submit certification of financial assurance or a decommissioning funding plan (10 CFR 30.35(e)). Regulatory Guide 3.66,[\(4\)](#) "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, provides sample documents for financial mechanisms. The recommended wording for a Statement of Intent for government licensees is shown below.

Suggested Wording for a Statement of Intent for a Government Licensee

[DATE]

TO: U.S. NUCLEAR REGULATORY COMMISSION

WASHINGTON, DC 20555 [or appropriate regional address]

STATEMENT OF INTENT

As [Title] of [Licensee Name] I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by U. S. Nuclear Regulatory Commission Material License No. [License Number] This authority is established by [Name of Document(s) Governing Control of Funds]. Within this authority, I intend to have funds made available when necessary in an amount up to [Dollar Amount] to decommission [Description of Facilities]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [Name of Documents] is attached as evidence that I am authorized to represent [Licensee Name] in this transaction.

[SIGNATURE]

[NAME]

[TITLE]

Attachment: As stated

Appendix G: Model Training Program

Model Training Program Course Content

Training may be in the form of lecture, videotape, or self-study, and emphasizes practical subjects important to the safe use of the self-shielded irradiator:

- **Radiation Safety**
 - Radiation vs. contamination
 - Internal vs. external exposure
 - Biological effects of radiation
 - Types and relative hazards of radioactive material possessed
 - ALARA concept
 - Use of time, distance, and shielding to minimize exposure
 - Use of radiation detection instruments.
- **Regulatory Requirements**
 - Locations of use and storage of radioactive materials
 - Material control and accountability
 - Annual audit of radiation safety program
 - License conditions, amendments, renewals
 - Transfer and disposal
 - Record keeping
 - Handling incidents
 - Licensing and inspection by regulatory agency
 - Need for complete and accurate information
 - Employee protection
 - Deliberate misconduct.

- Practical Explanation of the Theory and Operation for Each Irradiator Possessed by the Licensee
 - Routine vs. non-routine maintenance
 - Operating and emergency procedures
 - Prior events involving self-shielded irradiators.

Instructor's Qualifications

The individual preparing and conducting training is qualified as RSO or authorized user on a self-shielded irradiator license before giving training.

Training Assessment

Management will ensure that potential RSOs and authorized users are qualified to work independently with each type of the licensee's irradiators. This may be demonstrated by written or oral examination or by observation.

Appendix H: Typical Duties and Responsibilities of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license; see [Figure 8.1](#). Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures
- Possession, installation, relocation, use, storage, repair, and maintenance of self-shielded irradiators are consistent with the limitations in the license, the Sealed Source and Device Registration Certificate(s), and manufacturer's written recommendations

and instructions

- Safety consequences are analyzed before conducting any activities involving repair, use, maintenance, installation, or relocation, which were never previously analyzed
- Individuals installing, relocating, using, maintaining, or repairing self-shielded irradiators are trained and authorized (as described in the license application)
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Self-shielded irradiators are properly secured
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public
- Proper authorities are notified of incidents such as damage to or malfunction of self-shielded irradiators, fire, or theft
- Unusual occurrences involving the self-shielded irradiators (e.g., malfunctions or damage) are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken
- Radiation safety program audits are performed at least annually and documented
- When the licensee identifies violations of regulations or license conditions or program weaknesses, the licensee develops, implements, and documents corrective actions
- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained

- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner

Appendix I: Information Needed to Support Applicant's Request to Perform Non-Routine Maintenance

Information Needed to Support Applicant's Request to Perform Non-Routine Maintenance

Non-routine maintenance includes repairs, removal, replacement, or alterations involving:

Electrical and mechanical systems and components that control source or shielding movement

- Self-shielded irradiator's shielding or sealed source(s)
- Safety interlocks
- Any other component which may affect safe operation of the device
- Any other activities during which personnel could receive radiation doses exceeding NRC limits.

See [Figure 8.7](#). If this maintenance or repair is not performed properly with attention to radiation safety principles, the self-shielded irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits. Non-routine maintenance should be performed only by qualified and specifically authorized individuals. Self-shielded irradiator licensees should conduct these operations only after their procedures have been evaluated and specifically approved by license condition. Also, any non-manufacturer supplied replacement components need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration.

Accordingly, applicants wishing to perform non-routine maintenance must provide the following information, as appropriate:

- Describe the types of non-routine maintenance to be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

- Identify who will perform non-routine maintenance, their training and experience, and why they are competent to perform non-routine maintenance. Adequate training and experience includes the following:
 - previous experience in non-routine maintenance and radiation safety training
 - vendor maintenance certification
 - technician(s) using pre-planned procedures with direct health physics supervision.
- Submit procedures for non-routine maintenance. These procedures should ensure the following:
 - doses to personnel and members of the public are within regulatory limits and ALARA
 - the source is secured against unauthorized access or removal
 - appropriate labels and signs are used
 - manufacturer's written instructions and recommendations are followed
 - the self-shielded irradiator functions as designed and source integrity is not compromised
 - any non-manufacturer supplied replacement components are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration.
- Confirm that individuals performing non-routine maintenance on irradiators will always wear both whole body and extremity monitoring devices.
 - Verify possession of at least one instrument that meets the description for survey meters used with moving-source irradiators in the "Radiation Monitoring Instrument Specifications" section of Appendix K in draft NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-shielded Irradiator Licenses," dated October 1997
- Describe steps to be taken to ensure that radiation levels in areas where non-routine maintenance will take place do not exceed 10 CFR 20.1301 limits. For example, applicants can do the following:
 - commit to performing surveys with a survey instrument (as described above);
 - specify where and when surveys will be conducted during non-routine maintenance; and
 - commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 10 CFR 20.2103.

Appendix J: Suggested Self-Shielded Irradiator Audit Checklist

Annual Radiation Protection Self-Shielded Irradiator Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to the licensee's activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit _____

Date of Last Audit _____

Next Date Audit _____

Auditor: _____

Date _____

&nbs p; ; (Signature)

Management Review _____

Date _____

&nbs p; ; (Signature)

A. AUDIT HISTORY

1. Were previous audits conducted annually? [10 CFR 20.1101]
2. Were records of previous audits maintained? [10 CFR 20.2102]
3. Were any deficiencies identified during last two audits or two years, whichever is longer?
4. Were corrective actions taken? (Look for repeated deficiencies).

B. ORGANIZATION AND SCOPE OF PROGRAM

1. Radiation Safety Officer
 - a. If the RSO was changed, was license amended?
 - b. Does new RSO meet NRC training requirements?
 - c. Is RSO fulfilling his/her duties?

- d. To whom does RSO report?
- 2. Licensed Material
 - a. Does the license authorize all of the NRC-regulated radioactive material contained in self-shielded irradiators?
 - b. Does the total amount of radioactive material possessed require financial assurance? [10 CFR 30.35(a)]
- 3. Are the self-shielded irradiators as described in the Sealed Source and Device (SSD) Registration Certificate? Have copies of (or access to) SSD Certificates? Have manufacturers' manuals for operation and maintenance? [10 CFR 32.210]
- 4. Are the actual uses of self-shielded irradiators consistent with the authorized uses listed on the license?
- 5. If the mailing address or places of use changed, was the license amended?
- 6. If control of license transferred or bankruptcy filed, was NRC prior consent obtained or notification made, respectively?

C. TRAINING AND INSTRUCTIONS TO WORKERS

- 1. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per [10 CFR 19.12]? Was refresher training provided, as needed [10 CFR 19.12]?
- 2. Did each authorized user and person independently performing routine or non-routine maintenance attend license-required training before working with self-shielded irradiators?
- 3. Are training records maintained for each individual?
- 4. Did interviews with workers reveal that they know the emergency procedures and repair, maintenance, and relocation limitations?
- 5. Did this audit include observations of operators using the self-shielded irradiators? Performing routine or other authorized maintenance?
- 6. Did the audit identify any operator error in reporting maintenance and repair or operation issues to the RSO for review before starting work?

D. RADIATION AND SURVEY INSTRUMENTS

- 1. Describe the survey instruments possessed:
 - a. Do they meet the NRC's criteria?
 - b. Are they appropriate for the source type(s)?
 - c. Are they checked for function before use?
 - d. If they are used with moving-source irradiators or during non-routine maintenance, are they calibrated as required? [10 CFR 20.1501]
- 2. If the licensee does not possess a survey meter, are specific plans made to have one available?
Location: Location/Operation verified:

3. Are calibration records, if required, maintained? [10 CFR 20.2103(a)]
4. For J. L. Shepherd Mark I or Model 81-22 irradiator: check for compliance with license condition

E. SELF-SHIELDED IRRADIATOR INVENTORY AND LOCATION

1. Is a record kept showing the receipt of each self-shielded irradiator? [10 CFR 30.51(a)(1)]
2. Has the location(s) changed since the last audit?

F. PERSONNEL RADIATION PROTECTION

1. Are ALARA considerations incorporated into the radiation protection program? [10 CFR 20.1101(b)]
2. Is documentation kept showing that unmonitored users receive $\leq 10\%$ of limit? [10 CFR 20.1502(a)]
3. Did unmonitored users' activities change during the year which could put them over 10% of limit?
4. If yes to 3. above, was a new ALARA evaluation performed?
5. Is external dosimetry required (user receiving $>10\%$ of limit)? Is dosimetry provided to users?
 - a. If processed dosimetry:
 - i. Is the dosimetry supplier NVLAP approved? [10 CFR 20.1501(c)]
 - ii. Are dosimetry reports reviewed by the RSO when they are received?
 - b. If self-reading dosimeters:
 - i. Have a range of zero to at least 2 mSv (200 mrem)?
 - ii. Are checked at periods not to exceed one year for correct response to radiation?
 - iii. Are read within $\pm 20\%$ of the true radiation exposure?
 - iv. Are used under a program that prescribes action to evaluate the individual's dose?
6. Are the dosimeters exchanged or read at the license required frequency?
7. Are the records NRC Forms or equivalent? [10 CFR 20.2104(d), 10 CFR 20.2106(c)]
 - a. NRC-4 "Cumulative Occupational Exposure History" completed?
 - b. NRC-5 "Occupational Exposure Record for a Monitoring Period" completed?
8. Declared pregnant worker/embryo/fetus
 - a. If a worker declared her pregnancy, did licensee comply with 10 CFR 20.1208?
 - b. Were records kept of embryo/fetus dose per 10 CFR 20.2106(e)?
9. Are records of exposures, surveys, monitoring, and evaluations maintained [10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2106]

G. PUBLIC DOSE

1. Are self-shielded irradiators located and used in a manner to keep doses below 1 mSv (100 mrem) in a year? [10 CFR 20.1301(a)(1)]
2. Has a survey or evaluation been performed per 10 CFR 20.1501(a)?
3. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
4. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? [10 CFR 20.1301(a)(2)]
5. Are self-shielded irradiators being used or stored in a manner that would prevent unauthorized access or removal? [10 CFR 20.1801]
6. Records maintained? [10 CFR 20.2103, 10 CFR 20.2107]

H. OPERATING AND EMERGENCY PROCEDURES

1. Have operating and emergency procedures been developed?
2. Do they contain the required elements?
3. Does each operator have a current copy of the operating and emergency procedures? Maintain copy at each irradiator's control panel or post notice indicating where to obtain copy?
4. Did any emergencies occur?
 - a. If so, were they handled properly by operator?
 - b. Were appropriate corrective actions taken?
 - c. Was NRC notification or reporting required? (10 CFR 20.2201, 10 CFR 20.2202, 10 CFR 20.2203)
5. For J.L. Shepherd Mark I or Model 81-22 irradiator: check for compliance with license condition

I. LEAK TESTS

1. Was each sealed source leak tested every 6 months (or at other license prescribed intervals)?
2. Was the leak test performed as described in correspondence with NRC and according to the license?
3. Are records of results retained with the appropriate information included?
4. Were any sources found leaking and if yes, was NRC notified?

J. MAINTENANCE OF SELF-SHIELDED IRRADIATORS

1. Are manufacturer's written procedures followed for routine (not safety critical) cleaning and lubrication and mechanical/electrical maintenance and repair of self-shielded irradiators?
2. Was non-routine maintenance performed?

3. If yes, was it performed according to license requirements (e.g., extent of work, individuals performing the work, procedures, dosimetry, survey instrument, compliance with dose limits)?
4. Since the last audit, did operator(s) report a need for non-routine maintenance and repair to the RSO before requesting or conducting the work?

K. TRANSPORTATION

1. Were self-shielded irradiator(s) or sources shipped since the last audit?
2. If so, were 10 CFR Part 71 requirements followed?
 - a. DOT-Type A or Type B packages used? [10 CFR Part 71, 49 CFR 173.415, 49 CFR 173.416(b)] If Type B, NRC Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? NRC-approved QA program?
 - b. Package performance test records on file? [49 CFR 173.415(a)]
 - c. Special form sources documentation? [49 CFR 173.476(a)]
 - d. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [49 CFR 172.403, 49 CFR 173.441]
 - e. Package properly marked? [49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324]
 - f. Package closed and sealed during transport? [49 CFR 173.475(f)]
 - g. Shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]
 - h. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} [49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604]
 - i. Secured against movement? [49 CFR 177. 834]
 - j. Placarded on vehicle, if needed? [49 CFR 172.504]
 - k. Proper overpacks, if used? [49 CFR 173.25]
 - l. Any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]
 - m. Irradiators manufactured before 1966
 - i. Were any shipped?
 - ii. Were NRC and DOT exemptions, if needed, received in advance?

L. AUDITOR'S INDEPENDENT SURVEY MEASUREMENTS (IF MADE)

1. Describe the type, location, and results of measurements.

2. Do any radiation levels exceed regulatory limits?

M. NOTIFICATIONS AND REPORTS

1. Was any radioactive material lost or stolen? Were reports made? [10 CFR 20.2201, 10 CFR 30.50]
2. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.50]
3. Did any overexposures and high radiation levels occur? Reported? [10 CFR 20.2203, 10 CFR 30.50]
4. If any events (as described in items a through c above) did occur, what was root cause? Were corrective actions appropriate?
5. Is the licensee aware of telephone number for NRC Emergency Operations Center? [(301) 816-5100]

N. POSTING AND LABELING

1. NRC-3 "Notice to Workers" posted? [10 CFR 19.11]
2. NRC regs., license documents posted or a notice posted? [10 CFR 19.11, 10 CFR 21.6]
3. Other posting and labeling? [10 CFR 20.1902, 10 CFR 20.1904, 10 CFR Part 21]

O. RECORD KEEPING FOR DECOMMISSIONING

1. Records kept of information important to decommissioning? [10 CFR 30.35(g)]
2. Records include all information outlined in [10 CFR 30.35(g)]?

P. BULLETINS AND INFORMATION NOTICES

1. NRC Bulletins, NRC Information Notices, NMSS Newsletters, received?
2. Appropriate training and action taken in response?

Q. SPECIAL LICENSE CONDITIONS OR ISSUES

1. Did auditor review any special license conditions?
2. Did auditor review any other issues (e.g., non-routine maintenance)?

R. DEFICIENCIES IDENTIFIED IN AUDIT; CORRECTIVE ACTIONS

1. Summarize problems/deficiencies identified during audit.
2. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Include date(s) when corrective actions are implemented.
3. Provide any other recommendations for improvement.

S. EVALUATION OF OTHER FACTORS

1. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (RSO) oversight?

2. RSO has sufficient time to perform his/her radiation safety duties?
3. Licensee has sufficient staff to support the radiation protection program?

Appendix K: Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications

Instrument(s) used with moving-source gamma irradiators must meet the following criteria:

- The instrument is a survey meter capable of detecting gamma radiation up to several hundred milliroentgens (mR) (more than 50 microcoulombs/kilogram) per hour which is:
 - In the licensee's possession
 - Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
 - Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State.

OR

- The instrument is a room monitor which:
 - Is in the licensee's possession
 - Is checked with a source of radiation at the beginning of each day of use to ensure that it will respond accurately to radiation and alarm at 0.02 mSv (2 mrem) per hour
 - Activates a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour

- Is positioned so it will detect any radiation escaping from the irradiator door yet still be visible to the irradiator operator when using the irradiator.

Instrument(s) used with fixed-source gamma irradiators (or beta irradiators) are:

- A survey meter capable of detecting gamma radiation (or beta radiation, as appropriate)
- In the licensee's possession or readily accessible in the event of an accident or malfunction which could reduce the shielding for the sealed source(s)
- Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
- Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State.

Model Survey Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that the individual has sufficient classroom and on-the-job training to show competency in performing independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel performing survey instrument calibration
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present
- Individuals conducting calibrations will wear assigned dosimetry
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

- A radioactive sealed source(s) used for calibrating survey instruments will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by National Institutes of Standards and Technology (NIST)
 - Approximate the same photon energy (Cs-137, Co-60) as the environment in which the calibrated device will be employed
 - Be strong enough to give an exposure rate of at least about 30 mR/hr (7.7 microcoulombs/kilogram per hour) at 100 cm [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of Co-60].
- The inverse square and radioactive decay law must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a)).
- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$.
- The three kinds of scales frequently used on radiation survey meters are calibrated as follows:
 - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately $1/3$ and $2/3$ of the decade.
 - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately $1/3$ and $2/3$ of the decade.

- Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points will be at approximately 1/3 and 2/3 of the decade.
- Readings above 1000 mR/hr (250 microcoulombs/kilogram per hour) need not be calibrated. However, such scales should be checked for operation and approximately correct response.
- Survey meter calibration reports will indicate the procedure used and the data obtained. The description of the calibration will include:
 - The owner or user of the instrument
 - A description of the instrument including the manufacturer's name, model number, serial number, and type of detector
 - A description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - or instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
 - For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
 - The exposure rate from a check source, if used
 - The person's name who performed the calibration and the date it was performed
- The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated.
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <http://www.ansi.org/>.

See the Notice of Availability (on the inside front cover of this draft report) to obtain a copy of Draft Regulatory Guide FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

Appendix L: Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in 10 CFR 20.1201. To demonstrate that dosimetry is not required, a licensee needs to have available, for inspection, an evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing frequent routine maintenance on the irradiator. However, for most new irradiators even these activities result in the individual's receiving minimal doses. A licensee will need to evaluate the doses which its workers might receive in performing these tasks to assess whether dosimetry is required.

EXAMPLE

The following is an example of an estimate of the dose received by the extremities and whole body of a person performing routine maintenance (cleaning and lubrication) on a self-shielded irradiator rotating drawer drive chain. The estimate is based on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer can provide the following types of information:

- Time needed to perform the entire procedure (e.g., 20 min)
- Extremity dose rate received by an individual, associated with the shielded source (e.g., 0.02 mSv/hr [2 mrem/hr] at contact with the shield)
- Time the hands were exposed to the shielded source (e.g., 3 min)
- Whole body dose rate received by an individual, associated with the shielded source (e.g., 0.01 mSv/hr [1 mrem/hr] at contact with the shield)
- Time the whole body is exposed to the shielded source (e.g., 20 min)

From this information, an estimate of the doses that the individual performing this procedure could receive is as follows:

- 0.001 mSv [0.1 mrem] to the hands
- Less than 0.0033 mSv [0.33 mrem] TEDE (whole body).

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 mrems) per year. If one of these procedures delivers 0.0033 mSv (0.33 mrem), then an individual could perform 1,515 of these procedures each year and remain within 10% of the applicable limit.

The applicable SDE (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 mrems) per year. If one of these procedures delivers 0.001 mSv (0.1 mrem), then an individual could perform 50,000 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if a licensee performs fewer than 1,515 routine maintenance procedures per year.

GUIDANCE TO LICENSEES

Licensees who wish to demonstrate that they are *not* required to provide dosimetry to their workers need to prepare a written evaluation similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may *not* be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of self-shielded irradiator(s) they intend to use; this information is generally available from the irradiator manufacturer or the SSD Registration Certificate maintained by the NRC and Agreement States.

Table L.1 may be helpful in documenting a licensee's evaluation.⁽⁵⁾

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new irradiators containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table L.1 Dosimetry Evaluation

Dosimetry Evaluation for _____ Model _____ Self-Shielded Irradiator			
A.	Time needed to perform the entire routine maintenance procedure.	_____ (minutes/60)	_____ hour
B.	Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the irradiator while the sealed source is in the shielded position.	_____ mrem/hr	
C.	Time the <i>hands</i> were exposed to the unshielded source.	_____ (minutes/60)	_____ hour
D.	Expected extremity dose rate received by the individual, determined using exposure rates measured at the typical distance that the hands would be from the sealed source during the routine maintenance procedure.	_____ mrem/hr	
Formula: (_____ # hours in Row A) x (_____ mrem/hr in Row B) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem *Whole Body Dose			
Formula: (_____ # hours in Row C) x (_____ mrem/hr in Row D) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem **Extremity Dose			
* Expected Whole Body Doses <u>less than</u> 500 mrem requires no dosimetry ** Expected Extremity Doses <u>less than</u> 5000 mrem requires no dosimetry			

Appendix M: Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable

Limits

Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.

Members of the public include persons who live, work, or may be near locations where self-shielded irradiator devices are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both portions of the regulation. For areas around self-shielded irradiator facilities, calculations or a combination of calculations and measurements

(e.g., using an environmental TLD) are often used to prove compliance.

Calculational Method⁽⁶⁾

The calculational method takes a tiered approach, going through a three-part process starting with a worst case situation and moving

toward more realistic situations. It makes the following simplifications: (1) each irradiator is a point source; (2) typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source and Device (SSD) Registration Certificate, ANSI N433.1,[\(7\)](#) "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiator (Category I)," or the manufacturer's literature; and (3) no credit is taken for any shielding found between the irradiator and the unrestricted areas.

Part 1 of the calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers the distance, the portion of time and dose rate while the sample is in transit, the portion of time and dose rate while the sample is not in transit, and the portion of time that the affected member of the public is present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculational method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example 1

To better understand the calculational method, we will examine Bugs-Away, Inc., a self-shielded irradiator licensee. Yesterday, the company's president noted that the new irradiator area is close to his secretary's desk and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with NRC's regulations.

The secretary's desk is near the wall separating the reception area from the designated, locked self-shielded irradiator room where the company has located its irradiator. Joe measures the distance from the self-shielded irradiator to the wall and assumes that the irradiator would have the maximum dose rate allowed under the ANSI N433.1: 10 mrem per hour at one meter. This is the maximum dose rate permitted while the sample is in transit (i.e., moving into or out of the irradiation position). [Figure M.1](#) is Joe's sketch of the areas in question, and Table M.1 summarizes the information Joe has on the irradiator.

[Figure M.1 Diagram of Office and Irradiator Area.](#)

Table M.1 Information Known about the Self-Shielded Irradiator

Description of Known Information	Cs-137 Self-Shielded Irradiator

Dose rate in mrem/hr encountered at specified distance from the irradiator (from ANSI N433.1)	10 mrem/hr at 1 meter (3.28 ft)
Distance in feet to secretary's chair	15 ft

Example 1: Part 1

Joe's first thought is that the distance between the irradiator and the secretary's chair may be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a worst case approach, he assumes: 1) the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit, and 2) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from the self-shielded irradiator as shown in Table M.2 below.

Table M.2 Calculational Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator

[Table M.2 Calculational Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator](#)

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.48 mrem in an hour, but notes that an individual could receive a dose of 4,200 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit). He then recalculates the annual dose received.

Table M.3 Calculational Method, Part 2: Annual Dose Received from Self-Shielded Irradiator

[Table M.3 Calculational Method, Part 2: Annual Dose Received from Self-Shielded Irradiator](#)

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again Joe reviews his assumptions and recognizes that the irradiator is not constantly in use nor is the sample continuously in transit during an irradiation cycle when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

Table M.4 Calculational Method, Part 3: Summary of Information

[Table M.4 Calculational Method, Part 3: Summary of Information](#)

Table M.5 Calculational Method, Part 3: Annual Dose Received from Irradiator

[Table M.5 Calculational Method, Part 3: Annual Dose Received from Irradiator](#)

Joe is glad to see that the results in Step 23 show compliance with the 100 mrem in a year limit. Had the result in Step 23 been higher than 100 mrem in a year, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding⁽⁸⁾ located between the irradiator area and the secretarial workstation -- such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., move irradiator within the use area, move the use area, move the secretarial workstation) and perform new calculations to demonstrate compliance
- Designate the area outside the use area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary as required by 10 CFR 19.12

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the irradiator area. Licensees also need to make

similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., moving the self-shielded irradiator closer to the secretarial workstation, adding a second irradiator, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

RECORD KEEPING: 10 CFR 20.2107 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement - Calculational Method

This method, which allows the licensee to take credit for shielding between the irradiator and the area in question, begins by measuring radiation levels in the areas, as opposed to using ANSI-N433.1 or manufacturer-supplied rates at a specified distance from each irradiator. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a "work year" of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs⁽⁹⁾ in unrestricted areas next to the irradiator area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

Example: 2

As in Example 1, Joe is the RSO for Bugs-Away, Inc., a self-shielded irradiator licensee. The company has one irradiator in a designated, locked area that adjoins an unrestricted area where a secretarial work station is located. See [Figure M.1](#) and Table M.2 for

information. Joe wants to see if the company complies with the public dose limits at the secretarial station.

Joe placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table M.6 Combination Measurement-Calculational Method

[Table M.6 Combination Measurement-Calculational Method](#)

Appendix N: Information for Applicants to Consider When Developing Operating and Emergency Procedures for Self-Shielded Irradiators

Elements of Operating Procedures Applicable to All Types of Self-Shielded Irradiators

- Analyze each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine whether special procedures in addition to those given by the manufacturer are required to ensure the safe operation of the irradiator.
- Prepare model-specific instructions for routine inspections, test procedures, and maintenance to ensure that all interlocks, devices, and components critical to the safe operation of the irradiator are functioning properly. (Prohibited actions such as changing the safety control system or removing the source should be stated.)
- Develop methods to maintain accountability (e.g., log book to record irradiator use) and to ensure that only authorized persons will use or have access to the irradiator (e.g., control access to the irradiator's keys or control access to the area where the irradiator is located).
- Define steps to take to keep radiation exposures ALARA.
- For each model irradiator, define step-by-step procedures on how to operate the irradiator and how to perform routine maintenance. Information may be extracted from the manufacturer's manual.

Specific Operating Procedures Applicable to Moving-Source Irradiators [\(10\)](#)

- The irradiator should not be used unless the licensee provides a calibrated and operable radiation survey meter or a room monitor for use with the irradiator.
- The irradiator door should not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
- Each room monitor should:
 - be operable at all times when the irradiator is in use
 - activate a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mem) per hour
 - be located to detect any radiation escaping from the irradiator door
 - be located so that it is visible to the irradiator user when next to the irradiator.
- If a room monitor is not installed, a survey meter should be used to:
 - determine the radiation level at the irradiator door when the door is closed
 - check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators should position themselves to minimize exposure to any radiation escaping from the open door.
- If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee should stop using the irradiator, restrict access to the area housing the irradiator, immediately notify the RSO, and determine if a report to NRC is required.
- The licensee should not attempt to repair or authorize others to attempt to repair the irradiator except as specifically authorized in a license issued by NRC.

Elements of Emergency Procedures Applicable to All Types of Self-Shielded Irradiators

- Leave the irradiator area (to reduce radiation exposure).
- Control access to the area (e.g., lock door).
- Contact responsible individuals (e.g., names, phone numbers of RSO, irradiator manufacturer, emergency response organizations such as fire department, NRC).
- Take additional steps, dependent on the specific situations (e.g., surveys).
- As appropriate, require timely reporting to NRC

Copies of operating and emergency procedures should be provided to all users. Post a current copy at each irradiator's control panel. If posting the procedures is not practicable, post a notice describing the document(s) and where it may be examined.
--

Appendix O: Model Leak Test Program

Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.

Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.

- A NaI(Tl) well counter system with a single or multi-channel analyzer will be used to count samples from irradiators containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system will be used to count samples from irradiators containing beta-emitters (e.g., Sr-90).

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as self-shielded irradiator serial number, radionuclide, activity.

If available, use a survey meter to monitor exposure.

- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Becquerels (0.005 microcurie) of the radionuclide in the irradiator.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to primary radiation standards such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$$

where: cpm = counts per minute

std = standard

bkg = background

Bq = Becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example:
$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$$

Sign and date the list of sources, data, and calculations. Retain records for 3 years (10 CFR 20.2103(a)).

If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify NRC.

Appendix P: Transportation

Part 1 - Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of typical self-shielded irradiators that are shipped as Type A or Type B quantities are as follows:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities

- Shipping Papers 49 CFR 172.200-204: general entries, description, additional description requirements, shipper's certification
- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard
- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.800, etc.
- Shippers - General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A_1 and A_2 ..., table of A_1 and A_2 values for radionuclides, radiation level limit, requirements for USNRC-approved packages (Type B), quality control requirements prior to each shipment..., approval of special form radioactive materials
- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 2 - Sample Bill of Lading

[Straight Bill of Lading](#)

Part 3 - Irradiators Built Before 10 CFR Part 71 Regulation Implementation

Irradiators Built Before 10 CFR Part 71 Regulation

Implementation before the adoption of the requirements of 10 CFR Part 71 in 1966, irradiators could be transported without being evaluated under the hypothetical accident conditions now incorporated in 10 CFR Part 71. Unlike most post-1966 irradiators, pre-1966 irradiators are not certified shipping packages. Transport of pre-1966 units may require transferring the sealed source from the irradiator to a Type B package or the use of a certified package for the irradiator containing the sealed sources.

NRC will consider a licensee's request for an exemption for a one-time shipment according to 10 CFR 71.8 *only* if these options are not viable.

An exemption may be granted if the request is authorized by law and will not endanger life or property or the common defense and security. In this case, an exemption request should demonstrate the need for the exemption, describe why alternatives considered are not viable, specify from what requirement(s) an exemption is requested and the period for which the exemption is requested, and describe steps taken to ensure that the shipment will not endanger life or property or the common defense and security (e.g., steps to minimize accident risk and to respond to a transportation accident). Typically, approved requests are for a limited period (e.g., 30 days).

Circumstances vary, but additional information supporting an exemption request may include the following:

- Manufacturer's name and model number of the irradiator, the type and activity of radioactive material to be transported, and brief description of proposed trip (starting and ending points and approximate distance)
- Engineering drawings of irradiator
- Consideration of the following:
 - DOT's hazardous material routing requirements

- Transport during time of low road usage
 - Use of good roads and avoidance of residential areas to maximum extent possible
 - Accompaniment of shipment by escort knowledgeable in the use of radiation survey instruments
 - Provision of escort with appropriate survey instruments and supplies to permit the establishment of a radiation exclusion area
 - Written procedures to be followed by the escort in an emergency situation.
 - Use of exclusive-use vehicle and shoring to limit movement of package during transport
 - Notification of State radiological health officials and local fire department of time and route of shipment.
- Planned date of shipment

Before applying to the NRC for its approval, the licensee should contact the radiological health organization within each State through which the shipment will be made to confirm the points of contact and to discuss the proposed controls for the shipment. Contact NRC's regional offices (see [Figure 2.1](#)) for the name and telephone number of appropriate State officials. In several previous cases, short distance shipment of irradiators have been successfully made with the cooperation of State officials.

NRC Headquarters staff must review these requests, which are typically requests to amend materials (Part 30) licenses. Licensees should address their requests, accompanied by the amendment fee specified in 10 CFR 170.31, to the appropriate Regional Office. The Regional Office will refer the request to NRC Headquarters staff for review by the Package Certification Section, Spent Fuel Project Office (SFPO). If the exemption is approved, SFPO staff will provide the language for the license condition.

In addition to an NRC exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

Response from Applicant:

Demonstrate that the request is authorized by law and will not endanger life or property or the common defense and security.

AND

The following:

- Establish that the irradiator was built before 1966
- Explain why an approved package cannot be used, the alternatives considered, and why each is not viable
- Specify from what requirement(s) an exemption is requested and the period for which the exemption is requested
- Describe procedures, controls, and other actions to be taken to ensure that the shipment will not endanger life or property or the common defense and security.

Appendix Q: Sample Self-Shielded Irradiator License

NRC FORM 374

MATERIAL LICENSE		
PAGE NUMBER/NAME	GIF FILE	TIF FILE
Page 1/Materials License A and B	Form374 - 1	Form374 - 1
Page 2/Supplementary Sheet - C and D; Item 9 - Authorized Use	Form374 - 2	Form374 - 2
Page 3/Authorized Use (Continued); Conditions 10 through 13C	Form374 - 3	Form374 - 3
Page 4/Condition 13 (Continued); Conditions 14 through 16	Form374 - 5	Form374 - 5
Page 5/Conditions 17 through 18C (iv)	Form374 - 6	Form374 - 6
Page 6/Condition 18 (Continued); Conditions 19 through 20B	Form374 - 7	Form374 - 7
Page 7/Condition 21	Form374 - 8	Form374 - 8

Appendix R: Checklist for Self-Shielded Irradiator Application

Item 1: Action Type

ACTION TYPE:	ADMINISTRATIVE REVIEW:
<input type="checkbox"/> New	<input type="checkbox"/> Current guidance used
<input type="checkbox"/> Amendment	<input type="checkbox"/> References in application based on current regulations
<input type="checkbox"/> Renewal	<input type="checkbox"/> All referenced attachments included
	<input type="checkbox"/> Signature on application

Item 2: Legal Identity

NAME:	
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Items 2 & 3: Address

LOCATION OF USE/STORAGE ADDRESS:	MAILING ADDRESS:

Item 4: Person to be Contacted about this Application

CONTACT PERSON:	
TELEPHONE NUMBER:	

Items 5 and 6: Material to be Possessed and Uses

[Items 5 and 6: Material to be Possessed and Uses](#)

Items 7 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Management

[Items 7 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Management](#)

1. Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically at the following address: www.ansi.org. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (1-800-553-6847).
2. See "Amendments and Renewals to a License" later in this document. Licensees may request an amendment to an existing license to add authorization for a self-shielded irradiator.
3. For ease of use by most irradiator licensees, this table uses only conventional units. The conversion to SI units is: 1 Curie = 37 gigabecquerels.
4. See the Notice of Availability (on inside front cover of this draft report) to obtain copies of Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," (dated June 1990).
5. For ease of use by most irradiator licensees, this table uses conventional units. The conversion to SI units is: 1 mrem = 0.01 mSv
6. For ease of use by most self-shielded irradiator licensees, the examples in this Appendix use conventional units. The conversions to SI units are as follows: 1 ft = 0.305 m; 1 mrem = 0.01 mSv.
7. Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically at the following address: www.ansi.org. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 1-800-553-6847.
8. National Council on Radiation Protection and Measurements (NCRP) Report No. 49, "Structural Shielding Design and Evaluation for

Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV," contains helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

9. TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.

10. These procedures are required for licensees authorized for J. L. Shepherd Mark I or Model 81-22 irradiator.